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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,366	05/10/2002	Mie Takahashi	967-026	1103

7590 01/19/2007
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EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/049,366	Applicant(s) TAKAHASHI ET AL.	
	Examiner Leon Y. Lum	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 24-27 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 24-27, and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed October 19, 2006 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11, 24-27, and 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims in *In re Wands*, 8 USPQ2d 1400.

The nature of the invention – the invention is directed towards a biosensor having a porous material, a reagent holding part, a carrier that carries a cell shrinkage reagent, and a reaction layer chromatographically downstream of the carrier that permits shrunk cell components of a liquid specimen to permeate together with the liquid specimen in a mixed state. The invention therefore comprises a biosensor made of a porous material and having three compartments, one of which holds a cell-shrinking reagent. There is no requirement of a specific orientation of the biosensor or a pore size of the porous material.

The state of the prior art –Killeen et al (US 5,166,501) (hereinafter “Killeen”) discloses a biosensor with two main compartments, an overlay membrane and a detection zone, wherein the detection zone can include a Liotta-type arrangement of a labeled reagent zone and a detection zone. The overlay membrane, the Liotta labeled reagent zone, and the Liotta detection zone are therefore considered to be analogous to the claimed carrier, reagent holding part, and reaction layer. See column 5, lines 5-14 and column 8, lines 51-58. Killeen also teaches cell-shrinking reagents such as sodium chloride and potassium chloride in the overlay membrane that render cells rigid and unable to pass through from the overlay membrane to the detection zone. See column 5, lines 48-63. Killeen further teaches that the biosensor is comprised of a porous material. See column 5, lines 25-35.

The predictability or lack thereof in the art – there is a low predictability in the art for a biosensor having the claimed embodiments and cell-shrinking reagent to allow, as claimed, shrunk cells to permeate with the liquid specimen from the carrier part to the

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reaction layer. The specification, on page 21, describes the best mode for accomplishing the claimed method and includes the disclosure that the cell-shrinking reagent is an inorganic salt, including sodium chloride and potassium chloride, and the reaction layer 4 (referring to Figures 1-2) is "made of nitrocellulose or the like," indicating that the material of the claimed biosensor encompasses porous materials. The claimed invention therefore is a biosensor that allows the cell-shrinking reagent to osmotically shrink cells and then to allow them to penetrate the porous materials and flow into the reaction layer. However, the evidence presented in the prior art contradicts this situation. As described above, Killeen teaches that a biosensor with the exact same embodiments comprising the claimed biosensor, including the same type of biosensor material (i.e. porous matrix) and cell-shrinking reagent (i.e. sodium chloride). But instead of teaching that shrunk cells permeate into the reaction layer, Killeen teaches that the shrunk cells are stuck in the overlay membrane and do not proceed into the detection zone. This disclosure therefore directly provides prior art evidence that there is a low predictability of being able to make and use the invention as claimed by Applicants.

The amount of direction or guidance present – besides the best mode description on page 21, there is a lack of direction and guidance in the specification to make and use the invention as claimed. Although the general compartments and materials necessary to create the biosensor are disclosed, specific details are missing that would allow one of ordinary skill in the art at the time of the invention to provide a biosensor that is able to allow shrunk cells to permeate through a porous matrix. For example,

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porous materials are quite varied and can come in a variety of dimensions. Because a pore size is not given, it is unclear how large the pores must be for shrunk cells to be able to pass through the matrix. This problem is compounded by the fact that it is unclear how much the cells are shrunk by the cell-shrinkage reagent. Does concentration of the reagent affect the degree of shrinkage and therefore the necessary pore size?

The quantity of experimentation necessary – it would be undue experimentation for one of ordinary skill in the art to make and use the invention as claimed since that person would have to find a way to resolve the apparent bar against shrunk cells from proceeding through a porous matrix once they shrink and become rigid and are therefore no longer malleable enough to squeeze through the pores. As discussed above, the two-fold approach of determining the optimal cell-shrinking reagent and pore size would require a great deal of experimentation, thereby rendering it undue for one of ordinary skill in the art at to make and use the invention as claimed.

The relative skill of those in the art – the skill of one of ordinary skill in the art at the time of the invention is high.

The breadth of the claims – the claims are directed towards a biosensor having a porous material, a reagent holding part, a carrier that carries a cell shrinkage reagent, and a reaction layer chromatographically downstream of the carrier that permits shrunk cell components of a liquid specimen to permeate together with the liquid specimen in a mixed state.

Due to the undue experimentation required for one of ordinary skill in the art at the time of the invention to make and use the invention as claimed, especially in light of prior art teaching contradicting the claimed invention, the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

4. Claims 1-11, 24-27, and 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added limitation "wherein the shrunk cell components are made smaller but are not functionally destroyed by said cell shrinkage reagent" lacks support in the specification. Although the specification does provide support for a cell shrinkage reagent, there is no disclosure that the reagents would shrink cells without functionally destroying them. The specification seems to concern only the fact that the cells are shrunk. Nowhere is there mention on the viability or functionality of the cells after they are shrunk. Therefore, lacking disclosure on whether shrunk cells retain functionality after being exposed to the cells shrinkage reagents, the newly added limitation is not supported by the specification and is considered to be new matter.

Response to Arguments

5. Applicant's arguments with respect to claims 1-11, 24-27, and 31-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon Y. Lum
Patent Examiner
Art Unit 1641



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